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10/527,557	11/25/2005	Carl N. Kraus	015280-474200US	7454

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EXAMINER
KENNEDY, NICOLETTA

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/527,557	KRAUS ET AL.	
	Examiner	Art Unit	
	Nicoletta Kennedy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-30 are currently pending.

Priority

This application, filed March 10, 2005, is a national stage entry of PCT/US03/28889, filed September 12, 2003 and claims priority to provisional application 60/410,601, filed September 12, 2002. The instant claims are supported by the provisional application.

Election/Restrictions

1. Applicant's election with traverse of the restriction in the reply filed on December 16, 2009 is acknowledged. The traversal is on the ground(s) that unity of invention is not broken by the cited art. Applicants' remarks are acknowledged, however, in view of the prior art applied below in the instant office action, the special technical feature of claim 1 does not make a contribution over the prior art and therefore the technical feature recited in claim 1 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-13 and 30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 16, 2009.

3. Claims 14-29 are under examination.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 28-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 28-29 provide for the use of capreomycin for manufacture of a medicament, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 28-29 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 28-29 are being treated as method claims for producing an aerosolized capreomycin for delivery to the lung and are therefore treated as such in the below art rejections.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Staveski et al. (US 6,372,752) (pub. Apr. 16, 2002) in view of Capreomycin (Drug Facts and Comparisons) (pub. 2002).

Regarding claim 14, Staveski et al. teach compounds which inhibit the mycobacterial enoyl-ACP reductase required for cell wall biosynthesis, thus inhibiting growth (abstract). The compounds are used in pharmaceutical compositions for treating a bacterial infection in a patient (abstract). When the bacterial infection is by *Mycobacterium tuberculosis*, capreomycin can be administered as it is a known compound for the treatment of tuberculosis (column 9, lines 55-66). The capreomycin may be administered by inhalation and is introduced with a suitable propellant or other suitable gas (column 11, lines 39-45). However, Staveski et al. fail to teach that capreomycin also prohibits *Mycobacterium tuberculosis* growth. Capreomycin cures this deficiency.

Capreomycin teaches that capreomycin is intended for use with other antitubercolous agents in pulmonary infections caused by capreomycin-susceptible strains of *Mycobacterium tuberculosis* (p. 1494).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Staveski et al. with those of Capreomycin to administer capreomycin to inhibit growth of *Mycobacterium tuberculosis*. One would have been motivated to do so because Staveski et al. suggest that capreomycin be administered along with the compounds of Staveski et al.'s invention to treat a bacterial infection of *Mycobacterium tuberculosis* and Capreomycin teaches that capreomycin is administered concomitantly with other antituberculous agents to treat capreomycin-susceptible strains of *Mycobacterium tuberculosis*. It is presumed that treatment, read in view of Staveski et al., means inhibit the mycobacterial enoyl-ACP reductase required for cell wall biosynthesis, thus inhibiting growth (abstract).

11. Claims 15-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staveski et al. (US 6,372,752) (pub. Apr. 16, 2002) in view of Capreomycin (Drug Facts and Comparisons) (pub. 2002) as applied to claim 14 above, and further in view of Montgomery et al. (US 6,387,886) (pub. May 14, 2002).

The combination of Staveski et al. and Capreomycin teach each limitation of claim 14 but fails to teach further detail regarding capreomycin in the formulation. Montgomery et al. cure this deficiency.

Regarding claim 15, Montgomery et al. teach a method for the treatment of severe chronic bronchitis comprising using a concentrated aminoglycoside formulation (abstract). The aminoglycosides used in the invention include streptomycin, (column 6, line 1), an aminoglycoside also taught to be useful in treating *Mycobacterium tuberculosis* by Staveski et al. (column 9, line 63). The aminoglycoside may be used in powder form (column 6, lines 55-64).

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to have combined the teachings of Staveski et al. and Capreomycin with those of Montgomery et al. to introduce a powder form of capreomycin into the inhaler. One would have been motivated to do so because Montgomery et al. teach the powder form of aminoglycosides, of which capreomycin is a species. Further, Montgomery et al. teach that streptomycin may be used this way and Staveski et al. teach that either capreomycin or streptomycin may be used to treat *Mycobacterium tuberculosis*. It would have been within the purview of a skilled artisan to substitute capreomycin for streptomycin because Staveski et al. teach that each are known to be used to treat *Mycobacterium tuberculosis*. Further, Montgomery et al. teach that the nebulized particles reach the alveoli (lower lungs), a common goal in treating *Mycobacterium tuberculosis.*

Regarding claim 16, Montgomery et al. teach that the aminoglycoside is in an aerosol or dry powder form and has a mass medium diameter bewteen and 1 and 5 microns (abstract). MPEP 2144.05 states that "[i]n the case where the claimed ranges 'overlap or lie inside ranges disclosed by the prior art' a *prima facie* case of obviousness exists" quoting *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). In the instant case, the claimed range overlaps the range disclosed by the prior art and is therefore prima facie obvious.

Regarding claim 17, Staveski et al. teach that for administration by inhalation, a suitable powder base such as starch, a polysaccharide, is used (column 11, lines 39-50).

Regarding claim 20, Staveski et al. teach compounds which inhibit the mycobacterial enoyl-ACP reductase required for cell wall biosynthesis, thus inhibiting growth (abstract). The compounds are used in pharmaceutical compositions for treating a bacterial infection in a patient (abstract). When the bacterial infection is by *Mycobacterium tuberculosis*, capreomycin can be administered as it is a known compound for the treatment of tuberculosis (column 9, lines 55-66). The capreomycin may be administered by inhalation and is introduced with a suitable propellant or other suitable gas (column 11, lines 39-45). Capreomycin teaches that capreomycin is intended for use with other antitubercolous agents in pulmonary infections caused by capreomycin-susceptible strains of *Mycobacterium tuberculosis* (p. 1494). Montgomery et al. teach that the aminoglycoside may be aerosolized (column 5, lines 3-4).

Regarding claim 24, Staveski et al. teach compounds which inhibit the mycobacterial enoyl-ACP reductase required for cell wall biosynthesis, thus inhibiting growth (abstract). The compounds are used in pharmaceutical compositions for treating a bacterial infection in a patient (abstract). When the bacterial infection is by *Mycobacterium tuberculosis*, capreomycin can be

administered as it is a known compound for the treatment of tuberculosis (column 9, lines 55-66). The capreomycin may be administered by inhalation and is introduced with a suitable propellant or other suitable gas (column 11, lines 39-45). Capreomycin teaches that capreomycin is intended for use with other antitubercolous agents in pulmonary infections caused by capreomycin-susceptible strains of *Mycobacterium tuberculosis* (p. 1494). Montgomery et al. teach that the aminoglycoside may be aerosolized (column 5, lines 3-4).

Therefore, it is the Examiner's position that the combination of Staveski et al., Capreomycin and Montgomery et al. have produced an aerosolized capreomycin formulation that would reduce the infectivity of the person to whom the formulation is administered. One of ordinary skill in the art would reasonably conclude that Staveski et al., Capreomycin and Montgomery et al.'s effect of administering a formulation also possesses the same structural and functional properties as those of the effect of administering a formulation claimed and, therefore, it appears that Staveski et al., Capreomycin and Montgomery et al. have produced an effect of administering a formulation to a person that is identical to the effect of administering a formulation to a person. Since the Patent and Trademark Office does not have the facilities for examining and comparing the claimed method and results thereof with the method and results thereof of Staveski et al., Capreomycin and Montgomery et al., the burden of proof is upon the Applicants to show an unobvious distinction between the structural and functional characteristics of the effect of administering a formulation and the effect of administering a formulation of the prior art. See In re Best, 562 F.2d 1252, 195 U.S.P.Q. 430 (CCPA 197) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

Regarding claims 18, 21-22, 25-26 and 28, Montgomery et al. teach that the aminoglycoside may be used in a dry powder inhaler, metered dose inhaler, or nebulizer (column 8, lines 46-47 and column 13, line 64).

Regarding claims 19, 23, 27 and 29, Montgomery et al. teach that the aminoglycoside may be used in a jet or ultrasonic nebulizer (column 13, line 65 to column 14, line 5).

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicoletta Kennedy whose telephone number is (571)270-1343. The examiner can normally be reached on Monday through Thursday 8:15 to 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Gollamudi Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. K./

Examiner, Art Unit 1611

/David J Blanchard/
Primary Examiner, Art Unit 1643